

Amendment to the Specification:

Please add the following **new** paragraph after paragraph [0087]:

In the sera of 46 patients with Systemic Lupus Erythematosus (SLE), the TBP-II levels were 4.04 ± 3.75 ng/ml, a value highly significant compared to the normal levels ($p < 0.001$). 29 out of the 46 patients with SEE had a TBP-II level higher than the mean \pm 2SD of normal values. A highly significant correlation was found between the TBP-II levels and the disease activity index developed by Symmonds, D.P.M. et al, Quarterly J. of Med, (1988), Vol. 69, pp. 927-937: $r = 0.62$, $p < 0.001$. A similar correlation was found between TBP-II and the classical marker of SLE activity, the anti-DNA antibodies ($r = 0.64$, $p < 0.001$) and between a major clinical manifestation of SLE activity, i.e., joint pains and TBP-II ($r = 0.54$, $p < 0.001$).

These results indicate that TBP-II may be useful as a sensitive marker of disease activity and a predictor of exacerbations in SLE patients, and thus may be useful in monitoring immune activation related to disease activity in these patients as well as in patients with other autoimmune diseases.

By the above ELISA method, the TBP-II levels in sera of patients with different types of cancer, were examined. In

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20 out of 34 patients (58.8%) with different types of cancer, the TBP-II levels were above the normal mean \pm 2SD. The difference between the TBP-II of cancer patients (4.16 ± 4.08 ng/ml) and healthy controls (1.48 ± 0.46 ng/ml) was highly significant statistically ($p < 0.001$).

These results indicate that TBP-II may prove a useful and universal marker of different types of cancer and may be applied in early detection of this condition. After cancer resection, normalization of TBP-II levels may be a marker of cure of the disease. An increase in TBP-II, after initial normalization, may be an early and sensitive universal marker of disease relapse.

14 pregnant women at term with eclampsia or pre-eclampsia had statistically significant higher TBP-II levels (2.91 ± 0.96 ng/ml) than 16 normotensive pregnant women (1.58 ± 0.52) as determined by the ELISA method ($p < 0.001$).